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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD., and VIIV HEALTHCARE UK (NO. 3) LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ AG, and LEK PHARMACEUTICALS D.D.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited (collectively, "Plaintiffs" or "ViiV") bring this action for patent infringement against Sandoz Inc., Sandoz AG, and Lek Pharmaceuticals d.d. ("Lek") (collectively, "Defendants" or "Sandoz").

THE PARTIES

1. Plaintiff ViiV Healthcare Company, a wholly owned subsidiary of ViiV Healthcare Limited, is a corporation organized and existing under the laws of the State of

Delaware, with a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709.

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, is a corporation organized and existing under the laws of Japan, with a principal place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

3. Plaintiff ViiV Healthcare UK (No. 3) Limited is a corporation organized and existing under the laws of the United Kingdom, with a registered office at 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom.

4. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of Colorado, with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

5. On information and belief, Defendant Lek Pharmaceuticals d.d. is a corporation organized and existing under the laws of Slovenia, with its principal place of business at Verovškova 57, 1526 Ljubljana, Slovenia.

6. On information and belief, Defendant Sandoz AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

7. On information and belief, Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

8. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 210916, and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA")

to market and sell that proposed generic product throughout the United States, including within this District.

NATURE OF THE ACTION

9. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' ANDA No. 210916, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of dolutegravir sodium tablets, eq. 50mg base ("Proposed ANDA Product"), which is a generic version of ViiV's TIVICAY® (dolutegravir) Tablets for Oral Use prior to the expiration of Plaintiffs' U.S. Patent No. 9,242,986 ("the '986 Patent").

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 et seq.

11. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of New Jersey and this District.

12. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

13. This Court has personal jurisdiction over Sandoz Inc. by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Sandoz Inc.: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) holds a Drug and Medical Device Certificate Registration from this State; (4) is a registered manufacturer and wholesaler in the State of New Jersey and is registered to do business in New Jersey; (5) has its principal place of business in the State of New Jersey; and (6) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Sanofi-Aventis U.S. LLC et al. v. Sandoz Inc.*, 3:16-cv-05678 (D.N.J.); *AMAG Pharmaceuticals, Inc. v. Sandoz Inc.*, 3:16-cv-01508 (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc. et al.*, 14-cv-03547 (D.N.J.); *Janssen Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, 1:11-cv-07247 (D.N.J.); *Shionogi & Co., Ltd. v. Sandoz Inc.*, 3:12-cv-07907 (D.N.J.).

14. This Court has personal jurisdiction over Sandoz AG by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Sandoz AG: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; and (2) enjoys substantial income from this State.

15. This Court has personal jurisdiction over Lek by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On

information and belief, Lek: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; and (2) enjoys substantial income from this State.

16. On information and belief, Defendants directly or through their subsidiaries manufacture, import, market, and sell generic drugs throughout the United States and in this judicial district.

17. On information and belief, Defendants acted in concert to develop and prepare ANDA No. 210916 within this District.

18. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of TIVICAY® (dolutegravir) Tablets for Oral Use throughout the United States and in this judicial district.

19. For the reasons set forth above, for the reasons set forth in the Court of Appeals for the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

21. Today, Plaintiffs contemporaneously filed a complaint against Defendants for patent infringement in the United States District Court for the District of Delaware. The resulting action ("the Delaware Action") is presently pending. A copy of the complaint in the Delaware Action, excluding exhibits, is attached hereto as Exhibit B. The Delaware complaint alleges essentially the same acts of infringement as the present complaint.

22. Under 28 U.S.C. §§ 1391(b), (c) and 1400(b), Defendants should be subject to venue in the District of Delaware; however, Defendants may assert that they are not subject to such venue.

23. Plaintiffs are therefore filing the instant complaint, which has identical infringement claims against Defendants as the Delaware Action, a so-called Hatch-Waxman "protective suit," to preserve the filing date of the Delaware Action. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 U.S.C. § 355(j)(5)(F)(ii).

THE PATENT-IN-SUIT

24. The '986 Patent, entitled "synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates," was duly and legally issued on January 26, 2016 and will expire on December 8, 2029. A copy of the '986 Patent is attached as Exhibit A. Shionogi & Co., Ltd. is the assignee of the '986 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '986 Patent.

FACTUAL BACKGROUND

TIVICAY® (dolutegravir) Tablets for Oral Use

25. TIVICAY® (dolutegravir) Tablets for Oral Use are approved by the FDA for the treatment of HIV-1 infection.

26. ViiV Healthcare Company is the holder of approved New Drug Application No. 204790 for TIVICAY® (dolutegravir) Tablets for Oral Use, containing 50 mg of dolutegravir (as dolutegravir sodium).

27. TIVICAY® (dolutegravir) Tablets for Oral Use are covered by one or more Claims of the '986 Patent, and the '986 Patent has been listed for NDA No. 204790 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

28. ViiV sells and distributes TIVICAY® (dolutegravir) Tablets for Oral Use in the United States pursuant to NDA No. 204790.

Defendants' ANDA No. 210916

29. By the Notice Letter dated October 27, 2017, Defendants notified Plaintiffs that Defendants, by submitting ANDA No. 210916 to the FDA seek approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '986 Patent, and that ANDA No. 210916 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '986 Patent is allegedly invalid, unenforceable and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

30. On information and belief, Defendants were necessarily aware of the Patent-in-Suit when ANDA No. 210916 was filed with a Paragraph IV Certification.

31. On information and belief, dolutegravir sodium as covered in one or more of the Claims of the '986 Patent is, and/or will be, present in the Proposed ANDA Product.

32. On information and belief, ANDA No. 210916 refers to and relies upon NDA No. 204790 for TIVICAY® (dolutegravir) Tablets for Oral Use, and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and TIVICAY® (dolutegravir) Tablets for Oral Use.

33. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for TIVICAY® (dolutegravir) Tablets for Oral Use. The instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,242,986

34. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-33 of this Complaint.

35. Defendants' October 27, 2017 Notice Letter provides only conclusory arguments of non-infringement with no information to evaluate those arguments.

36. In a November 13, 2017 email, Plaintiffs requested that Defendants agree to modify the Offer of Confidential Access related to ANDA No. 210916 to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of Claims 1-12 of the '986 Patent.

37. On November 14, 2017, Plaintiffs sent a revised Offer of Confidential Access to Defendants.

38. On November 15, 2017, Defendants sent a further revised Offer of Confidential Access to Plaintiffs.

39. On November 17, 2017, Plaintiffs returned an executed version of the revised Offer of Confidential Access to Defendants.

40. On November 21, 2017, Defendants produced materials purportedly related to ANDA No. 210916 to Plaintiffs.

41. On information and belief, the produced materials support that the Proposed ANDA Product infringes one or more Claims of the '986 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of dolutegravir sodium as covered in one or more of the Claims of the '986 Patent.

42. Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to

present to the Court evidence that Defendants infringe one or more Claims of the '986 Patent. *See Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).

43. Defendants' submission of ANDA No. 210916 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '986 Patent constitutes infringement of one or more Claims of the '986 Patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 210916 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

45. On information and belief, upon FDA approval of ANDA No. 210916, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

46. Upon FDA approval of ANDA No. 210916, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

47. On information and belief, Defendants had knowledge of the '986 Patent when they submitted ANDA No. 210916 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '986 Patent.

48. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

49. On information and belief, Defendants lacked a good faith basis for alleging non-infringement of Claims 1-12 and invalidity of Claims 1-12 of the '986 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that the '986 Patent is valid and enforceable;

b) Judgment that Defendants' submission of ANDA No. 210916 was an act of infringement under 35 U.S.C. § 271(e)(2) of one or more Claims of the '986 Patent;

c) Judgment that Defendants' making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '986 Patent, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the '986 Patent;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 210916 shall be a date that is not earlier than the expiration of the '986 Patent plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed ANDA Product until after the expiration of the '986 Patent plus any other exclusivity to which Plaintiffs are or become entitled;

f) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Plaintiffs of their reasonable costs and attorneys' fees incurred in connection with this action; and

g) Such further and other relief as this Court deems proper and just.

Dated: December 11, 2017

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

ViiV Healthcare Company, et al. v. Cipla Limited, et al.,
Civil Action No. 17-1670 (D. Del.);

ViiV Healthcare Company, et al. v. Mylan Pharmaceuticals Inc., et al.,
Civil Action No. 17-1671 (D. Del.);

ViiV Healthcare Company, et al. v. Mylan Pharmaceuticals Inc., et al.,
Civil Action No. 17-197 (N.D. W. Va.);

ViiV Healthcare Company, et al. v. Apotex Inc., et al.,
Civil Action No. 17-1634 (D. Del.);

ViiV Healthcare Company, et al. v. Lupin Limited, et al.,
Civil Action No. 17-1576 (D. Del.);

ViiV Healthcare Company, et al. v. Dr. Reddy's Laboratories, Inc., et al.,
Civil Action No. 17-1678 (D. Del.);

ViiV Healthcare Company, et al. v. Dr. Reddy's Laboratories, Inc., et al.,
Civil Action No. 17-11873 (D.N.J.);

ViiV Healthcare Company, et al. v. Dr. Reddy's Laboratories, Inc., et al.,
Civil Action No. 17-1737 (D. Del.);

ViiV Healthcare Company, et al. v. Dr. Reddy's Laboratories, Inc., et al.,
Civil Action No. 17-12374 (D.N.J.);

ViiV Healthcare Company, et al. v. Cipla Limited, et al.,
Civil Action No. 17-1741 (D. Del.); and

ViiV Healthcare Company, et al. v. Sandoz Inc., et al.,
Civil Action No. _____ (D. Del.).

Dated: December 11, 2017

Respectfully submitted,

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